DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5177

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-38704

February 12, 2001

Frank S. Chaves, Owner
Frank Chaves & Sons Dairy
12754 E. Harney Lane
Lodi, California 95240

WARNING LETTER

Dear Mr. Chaves:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation in Lodi, California, on January 19 and 22, 2001. The inspection revealed serious violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On October 25, 2000, you consigned a cow, identified with back tag number 93 DH 919 (USDA laboratory report number 405334), to be sold for human food through [redacted] USDA analysis of tissue samples collected from that cow identified the presence of the drug neomycin in the kidney at 9.20 parts per million (ppm). The USDA analysis also revealed the presence of sulfadimethoxine in the liver at 0.61 ppm and in the muscle at 0.82 ppm. Presently, the tolerance level for neomycin in the uncooked edible kidney tissue of cattle is 7.2 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.430). The tolerance level for sulfadimethoxine in the uncooked tissues of cattle is 0.10 ppm (Title 21 CFR, Part 556.640). Your use of neomycin and sulfadimethoxine in a cow resulted in the illegal drug residues found in the liver, muscle, and kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so

inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

2. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosage, dates of administration, and the pre-slaughter withdrawal time.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

You are adulterating the drug Albon brand of sulfadimethoxine within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. Your veterinarian prescribed Albon boluses and Biosol for the treatment of diarrhea in your cows. Your veterinarian also prescribed a withdrawal time of eight days for the Albon and twelve days for the Biosol prior to slaughter. Failure to comply with these withdrawal times is likely the cause of the neomycin and sulfadimethoxine residues in the cow you sold for slaughter.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our Sacramento office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, United States Food and Drug Administration, 650 Capitol Mall, Room 8-400, Sacramento, California 95814.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District

cc: [redacted]